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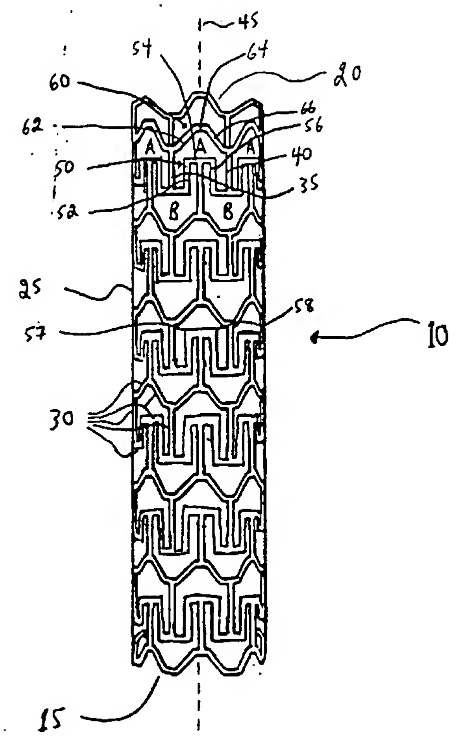
(54) **EXTENSEUR DILATABLE ET METHODE D'INSERTION**
(54) **EXPANDABLE STENT AND METHOD FOR DELIVERY OF SAME**



(57) Extenseur présentant une extrémité proximale et une extrémité distale reliées communiquant l'une avec l'autre. Une paroi tubulaire est disposée entre ces deux extrémités et l'axe longitudinal et une surface poreuse de la paroi sont définis par plusieurs éléments interreliés et placés de manière à définir un premier motif récurrent consistant en un polygone. Le polygone comporte deux parois latérales essentiellement parallèles à l'axe longitudinal : une première paroi concave comportant une première partie apicale, et une deuxième paroi concave comportant une deuxième partie apicale; ces deux parois étant reliées aux parois latérales. Au moins une des deux parties apicales est essentiellement plane. L'extenseur passe d'une première position rétractée à une deuxième position allongée, par l'application d'une pression radiale agissant vers l'extérieur. La présente invention a également trait à un extenseur bifurqué comportant le premier motif récurrent.

(57) An expandable stent comprising a proximal end and a distal end in communication with one another. A tubular wall is disposed between the proximal end and the distal end. The tubular wall having a longitudinal axis and a poroussurface defined by a plurality intersecting members arranged to define a first repeating pattern comprised of a polygon. The polygon has a pair of side walls substantially parallel to the longitudinal axis, a concave-shaped first wall having a first apex and a convex-shaped second wall having a second apex, the first wall and the second wall connecting the side walls. At least one of the first apex and the second apex is substantially flat. The stent is expandable from a first, contracted position to a second, expanded position upon the application of a radially outward force on the stent. A bifurcated stent including the first repeating pattern is also described.

ABSTRACT OF THE DISCLOSURE

An expandable stent comprising a proximal end and a distal end in communication with one another. A tubular wall is disposed between the proximal end and the distal end. The tubular wall having a longitudinal axis and a porous surface defined by a plurality intersecting members arranged to define a first repeating pattern comprised of a polygon. The polygon has a pair of side walls substantially parallel to the longitudinal axis, a concave-shaped first wall having a first apex and a convex-shaped second wall having a second apex, the first wall and the second wall connecting the side walls. At least one of the first apex and the second apex is substantially flat. The stent is expandable from a first, contracted position to a second, expanded position upon the application of a radially outward force on the stent. A bifurcated stent including the first repeating pattern is also described.

EXPANDABLE STENT AND METHOD FOR DELIVERY OF SAME

The present invention relates to an expandable stent and to a method for delivery of same.

Stents are generally known. Indeed, the term "stent" has been used interchangeably with terms such as "intraluminal vascular graft" and "expansible prosthesis". As used throughout this specification the term "stent" is intended to have a broad meaning and encompasses any expandable prosthetic device for implantation in a body passageway (e.g. a lumen or artery).

In the past six to eight years, the use of stents has attracted an increasing amount of attention due the potential of these devices to be used, in certain cases, as an alternative to surgery. Generally, a stent is used to obtain and maintain the patency of the body passageway while maintaining the integrity of the passageway. As used in this specification, the term "body passageway" is intended to have a broad meaning and encompasses any duct (e.g. natural or iatrogenic) within the human body and can include a member selected from the group comprising: blood vessels, respiratory ducts, gastrointestinal ducts and the like.

Initial stents were self-expanding, spring-like devices which were inserted in the body passageway in a contracted state. When released, the stent would automatically expand and increase to a final diameter dependent on the size of the stent and the elasticity of the body passageway. An example of such a stent was known in the art as the Wallstent™.

The self-expanding stents were found by some investigators to be deficient since, when deployed, they could place undue, permanent stress on the walls of the body passageway. Further, upon expansion, the stent would shorten in length in an unpredictable fashion thereby reducing the reliability of the stent. This led to the

development of various stents which were controllably expandable at the target body passageway so that only sufficient force to maintain the patency of the body passageway was applied in expanding the stent.

Generally, in these later systems, a stent, in association with a balloon, is delivered to the target area of the body passageway by a catheter system. Once the stent has been properly located (for example, for intravascular implantation the target area of the vessel can be filled with a contrast medium to facilitate visualization during fluoroscopy), the balloon is expanded thereby expanding the stent so that the latter is urged in place against the body passageway. As indicated above, the amount of force applied is at least that necessary to maintain the patency of the body passageway. At this point, the balloon is deflated and withdrawn within the catheter, and subsequently removed. Ideally, the stent will remain in place and maintain the target area of the body passageway substantially free of blockage (or narrowing).

A stent which has gained some notoriety in the art is known as the Palmaz-Schatz™ Balloon Expandable Stent (hereinafter referred to as "the Palmaz-Schatz stent"). This stent is discussed in a number of patents including United States patents 4,733,665, 4,739,762, 5,102,417 and 5,316,023, the contents of each of which are hereby incorporated by reference.

Another stent which has gained some notoriety in the art is known as the Gianturco-Roubin Flex-Stent™ (hereinafter referred to as "the Gianturco-Roubin stent"). This stent is discussed in a number of patents, including United States patents 4,800,882, 4,907,336 and 5,041,126, the contents of each of which are hereby incorporated by reference.

Other types of stents are disclosed in the following patents:

United States patent 5,035,706 (Gianturco et al.),

United States patent 5,037,392 (Hillstead),
United States patent 5,147,385 (Beck et al.),
United States patent 5,282,824 (Gianturco),
Canadian patent 1,239,755 (Wallsten), and
Canadian patent 1,245,527 (Gianturco et al.),

the contents of each of which are hereby incorporated by reference.

While these prior art stents have achieved a varying degree of success, the art is constantly in need of new stents having improved flexibility and stability while being able to be readily implanted with little or no trauma to the target lumen.

In our Canadian patent application number 2,134,997, the contents of which are hereby incorporated by reference, there is described an improved expandable stent. The stent comprises a tubular wall disposed between the proximal end and the distal end. The tubular wall has a longitudinal axis and a porous surface defined by a plurality intersecting members arranged to define a first repeating pattern. The first repeating pattern comprises a polygon having a pair of side walls substantially parallel to the longitudinal axis. A first concave-shaped wall and a second convex-shaped wall connect the side walls. The first wall and the second wall are equidistant along an axis which is parallel to the longitudinal axis. The stent is expandable from a first, contracted position to a second, expanded position upon the application of a radially outward force exerted on the stent.

As disclosed in the '997 application, the first repeating pattern can be implemented in, <u>inter alia</u>, a mono-tubular expandable stent and a bifurcated expandable stent.

While the stent disclosed in the '997 application is an advance in the art, in certain cases, a significant force is required to achieve expansion in the target body passageway. Further, implantation of the stent disclosed in the '997 application can

be difficult in certain situations where the unexpanded stent must travel through a significantly curved pathway to the target body passageway.

Accordingly, it would be desirable to have an improved stent which overcomes these disadvantages. It would be further desirable if the improved stent could be readily adapted, inter alia, to mono-tubular expandable stents and bifurcated expandable stents. The latter type of stents would be useful in treating aneurysms, blockages and other ailments. It would also be desirable if such a stent was relatively easy to implant. It would be further desirable if such a stent were capable of uniform expansion at relatively low pressure while obviating or mitigating longitudinal shrinkage thereof. It would be further desirable if such a stent were not susceptible to asymmetric internal coverage of the body passageway, a problem associated with "coil"-type stents - see, for example, United States patent 5,282,824 (Gianturco). It would be further desirable if such a stent was not susceptible to movement along the longitudinal axis of the body passageway during or after implantation.

It is an object of the present invention to provide a novel expandable stent which obviates or mitigates at least one of the above-mentioned disadvantages of the prior art.

It is another object of the present invention to provide a novel method for implanting an expandable bifurcated stent.

Accordingly, in one of its aspects, the present invention provides an expandable stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of intersecting members arranged to define a first repeating pattern comprised of a polygon having a pair of side walls substantially parallel to the longitudinal axis, a concave-shaped first wall having a first apex and a convex-

shaped second wall having a second apex, the first wall and the second wall connecting the side walls, at least one of the first apex and the second apex being substantially flat, the stent being expandable from a first, contracted position to a second, expanded position upon the application of a radially outward force on the stent.

In another of its aspects, the present invention provides an expandable bifurcated stent comprising a proximal end and a distal end in communication with one another, the proximal end comprising a primary passageway and the distal end comprising a pair of secondary passageways, the stent being expandable from a first, contracted position to a second, expanded position upon the application of a radially outward force exerted on the stent, each of the primary and secondary passageways comprising a tubular wall having a longitudinal axis and a porous surface defined by a plurality of intersecting members arranged to define a first repeating pattern comprised of a polygon having a pair of side walls substantially parallel to the longitudinal axis, a concave-shaped first wall having a first apex and a convex-shaped second wall having a second apex, the first wall and the second wall connecting the side walls, at least one of the first apex and the second apex being substantially flat, the stent being expandable from a first, contracted position to a second, expanded position upon the application of a radially outward force on the stent.

We have now discovered that the use of a specific repeating pattern in a porous stent is particularly advantageous. Generally, the repeating pattern is a polygon having a pair of side walls substantially parallel to the longitudinal axis of the tubular wall of the stent, and a concave-shaped first wall and a convex-shaped second wall connecting the side walls. As used throughout this specification, the terms "concave-shaped" and "convex-shaped" are intended to have a broad meaning and a shape having apex. Thus, the first wall has a first apex and the second wall

has a second apex. Thus, the first apex (i.e. of the concave-shaped first wall) is directed into the polygon whereas the second apex (i.e. of the convex-shaped second wall) is directed away from the polygon.

It is has been discovered that an improved stent results when the repeating pattern is designed such that at least one of the first apex and second apex is substantially flat. The advantages associated with the use of such a repeating pattern include the following:

1. The force required to expand the stent is substantially reduced;
2. The stent is subjected to less traumatic stress during expansion;
3. Plastic deformation of the stent during expansion is facilitated;
4. Construction of the stent is facilitated; and
5. Upon expansion of the stent, warpage of the first apex and the second apex is obviated or mitigated.

The provision of at least one of the first apex and the second apex being substantially flat results in the apex of the concave-shaped first wall and/or the convex-shaped second wall having a pair of shoulders. Preferably, these shoulders are rounded. The provision of such round shoulders results in the following additional advantages:

6. Mitigation of potential trauma to the target body passageway from: (i) endoluminal contents within the passageway, and (ii) the contours of the passageway;
7. The resulting expanded stent is more stream-lined and flow-directed which mitigates potential trauma to the target body passageway;

8. Further reduction in the force required to expand the stent;
9. An improved stent expansion ratio is achieved (i.e. ratio of expanded stent diameter at maximum expansion to unexpanded stent diameter);
10. Upon expansion of the stent, the concave-shaped first wall and the convex-shaped second wall are in a substantially orthogonal relationship to the longitudinal axis thereby improving the rigidity of the stent (this is very important to mitigate the occurrence of stent recoil); and
11. The pattern of the expanded stent improves the rheology of fluid flow in the body passageway.

Another preferred feature of the stent of the present invention is the provision of a strut connecting the first apex and the second apex. This feature mitigates lifting of the shoulders referred to above as the stent is flexed, for example, when passing the stent through a curved body passageway. The result of this is that potential trauma to the body passageway is mitigated since scraping of the body passageway by the shoulders is mitigated.

In a preferred embodiment, the strut is curved with respect to the longitudinal axis (this is described and illustrated hereinbelow). Preferably, the strut has length of up to about 35%, more preferably up to about 15%, even more preferably in the range of from about 2% to about 8%, most preferably in the range of from about 3% to about 7%, greater than the distance between the first apex and the second apex. This feature improves the lateral flexibility of the stent thereby facilitating implantation thereof.

In another preferred embodiment, the strut comprises a sinusoidal or S-shaped section. Preferably, the sinusoidal or S-shaped section is adjacent the

second apex of the polygon and the remaining portion of the strut is substantially straight. This feature improves the lateral flexibility of the stent thereby facilitating implantation thereof and may further mitigate longitudinal shortening of the stent upon expansion.

In another preferred embodiment, at least one, more preferably both, of the side walls of the polygon comprises a sinusoidal or S-shaped section. Preferably, the sinusoidal or S-shaped section is disposed at an end of the side wall. This feature improves the lateral flexibility of the stent thereby facilitating implantation thereof and may further mitigate longitudinal shortening of the stent upon expansion.

When a sinusoidal or S-shaped portion is disposed in the side walls and/or the sturt connecting the first apex and the second apex (if present), the precise shape of the portion is not particularly restricted and generally takes the form of an "S". Thus, the sinusoidal or S-shaped portion may be comprised of a pair of joined curved sections wherein each curved section has an arc of about 180° - i.e. this is illustrated in Figure 8 of the present application. The term "arc" denotes the angle from one end of the curved section to the other about the radical point of the curved section. Alternatively, the sinusoidal or S-shaped portion may be comprised of a pair of joined curved sections wherein each curved section has an arc of greater than 180° - this is illustrated in Figure 9 of the present application. Further, the pair of joined curved sections can be of the same size (this is illustrated in Figures 8 and 9 of the present application) or of differing size (this is illustrated in Figure 10 of the present application).

Yet another preferred feature of the stent of the present invention is the provision of one or both of the side walls of the polygon of the repeating pattern being curved. Preferably, both side walls are curved. Ideally, the curved side wall has length of up to about 35%, more preferably up to about 15%, even more

preferably in the range of from about 2% to about 8%, most preferably in the range of from about 3% to about 7%, greater than the distance between the termini of the concave-shaped first wall and the concave-shaped second wall. This feature improves the lateral flexibility of the strut thereby facilitating implantation thereof.

Preferably, both the strut and the side walls are curved. More preferably, each of the curved members are of substantially the same length.

Yet another preferred feature of the stent of the present invention is, in addition to the strut and side walls of the polygon being curved, the provision of all longitudinal walls of the polygon of the repeating pattern being curved. Thus, in this embodiment of the invention, the concave-shaped first wall comprises a pair of curved first apex walls connecting the first apex and the side walls of the polygon, and the convex-shaped second wall comprises a pair of curved second apex walls connecting the second apex and the side walls of the polygon. Ideally, the curved first apex walls and the curved second apex walls each have a length of up to about 35%, more preferably up to about 15%, even more preferably in the range of from about 2% to about 8%, most preferably in the range of from about 3% to about 7%, greater than the straight (i.e. non-curved) distance between the first apex and the side walls, and the second apex and the side walls, respectively. In this embodiment, it is further preferred to have substantially all adjacent curved walls in an annular section of the repeating pattern (i.e. of the struts, first apex wall, second apex wall and side walls) are substantially equidistant from one another. This preferred feature of the stent of the present invention even further enhances the lateral flexibility of the stent thereby further facilitating implantation thereof.

Yet another preferred feature of the stent of the present invention is provision a porous surface multiple designs. Specifically, in certain cases, it may be desirable to design the stent to varying degrees of relative flexibility and rigidity along the length thereof. Thus, the relatively flexible portion(s) of such a stent would

facilitate delivery of the stent to a target body passageway through a relatively tortuous route, while the relatively rigid portion(s) of the stent serves facilitate maintaining the patency of the body passageway. As will be discussed in more detail hereinbelow, this may be achieved by varying the repeating pattern design along the longitudinal length of the stent.

An aspect of the present invention relates to the provision of an expandable bifurcated stent. As used throughout this specification, the term "bifurcated stent" is intended to have a broad meaning and encompasses any stent having a primary passageway to which is connected at least two secondary passageways. Thus, trifurcated stents are encompassed herein. Further, one of the secondary passageways can be a continuation of the primary passageway with the result that the other secondary passageway is essentially a side branch to the primary passageway.

The stent of the present invention (bifurcated or mono-tubular) can further comprise coating material thereon. The coating material can be disposed continuously or discontinuously on the surface of the stent. Further, the coating may be disposed on the interior and/or the exterior surface(s) of the stent. The coating material can be one or more of a biologically inert material (e.g. to reduce the thrombogenicity of the stent), a medicinal composition which leaches into the wall of the body passageway after implantation (e.g. to provide anticoagulant action, to deliver a pharmaceutical to the body passageway and the like) and the like.

Preferably, the stent is coated with a biocompatible substance such as a biolized collagen/gelatin compound - see, for example, Emoto et al. in “Characterization of Rehydrated Gelatin Gels”, Artificial Organs, 15(1):29-34 (1991), the contents of which are hereby incorporated by reference. The use of

such a coating improves biocompatibility of the stent and facilitate fluid flow through and around the stent.

In another embodiment of the invention, the stent may be joined to a polymer material. Specifically, a polymer material may be extruded onto the stent in such a manner that it envelops at least a portion of the stent. This technique may be used to join two or more stents with a flexible polymeric tube. This technique may also be used to join a stent to another prosthetic device such as a tube, a graft and the like. Thus, in this embodiment of the invention, the stent is incorporated into an endoluminal prosthesis.

In yet another embodiment of the invention, the stent may be secured (e.g. by suturing) to an existing endoluminal prosthesis such as Gortex™ material or to biological material such as basilic vein. In this regard, securing of the stent to the existing endoluminal prosthesis or biological material may be facilitated by designing the stent such that an end of the stent comprises an annular row of the above-mentioned polygons is having a convex-shaped wall with a flat apex.

Embodiments of the present invention will be described with reference to the accompanying drawings wherein like numerals designate like parts and in which:

Figure 1 illustrates an exploded perspective view of a mono-tubular stent prior to expansion;

Figure 1A illustrates an exploded view of a portion of the stent illustrated in Figure 1;

Figures 2-10 each illustrate a two dimensional representation of various embodiments (not to relative scale) of a repeating pattern useful in the stent of the present invention; and

Figure 11 illustrates an ostial stenosis to which a preferred embodiment of the invention may be applied.

With reference to Figures 1, there is illustrated a stent 10. Stent 10 comprises a proximal end 15 and a distal end 20. Stent further comprises a tubular wall 25 disposed between proximal end 15 and distal end 20. As illustrated, tubular wall 25 is porous. The porosity of tubular wall 25 is defined by a plurality of intersecting members 30. Intersecting members 30 define a first repeating pattern designated A in Figure 1.

As illustrated and with further reference to Figure 1A, repeating pattern A is a polygon comprising a pair of side walls 35,40. Side walls 35,40 are substantially parallel to a longitudinal axis 45 of stent 10. Side walls 35,40 are connected by a concave-shaped wall 50 and a convex-shaped wall 60.

As illustrated, concave-shaped wall 50 is made up of a trio of segments 52,54,56. In the illustrated embodiment, segment 54 is the apex of concave-shaped wall 54. As is evident, segment 54 is a flat apex and results in the provision of a pair of substantially square shoulders 57,58 Convex-shaped wall 60 is made up of a trio of segments 62,64,66. In the illustrated embodiment, segment 64 is the apex of convex-shaped wall 60.

It will be appreciated by those of skill in the art that the provision of first repeating pattern A, as illustrated, necessarily defines and provides for a second repeating pattern B. It will also be appreciated by those of skill in the art that second repeating pattern B is a mirror image of first repeating pattern A taken along an axis (not shown) substantially normal to longitudinal axis 45. Thus, in the illustrated embodiments, adjacent rows of repeating pattern A and repeating pattern B may be considered to by interlocking polygons or "arrowheads".

It will be further appreciated by those of skill in the art that the shape of concave-shaped wall 50 and/or convex-shaped wall 60 can be modified without departing from the function and performance of the stent provided that at least one of concave-shaped wall 50 and convex-shaped wall 60 retain a substantially flat

apex. For example, the trio of segments can be replaced by a suitably curved or arcuate wall. Alternatively, more than three segments can be used to define concave-shaped wall 50 and/or convex-shaped wall 60. Other modifications will be apparent to those of skill in the art.

It will be further appreciated by those of skill in the art that various walls of first repeating pattern A and second repeating pattern B may be omitted (and even desired) at selected points along the body of the stent without departing from the spirit and scope of the invention. For example, it is possible to omit one or both of side walls 35 and 40 at selected points along the body of the stent with a view to improving the longitudinal flexibility of the stent. Further, it is possible to omit one or more of segments 62,64,66 at selected points along the body of the stent with a view to improving the lateral flexibility of the stent.

Still further, the stent depicted in Figure 1 can be modified to omit, on a selected basis, first repeating pattern A and/or second repeating B with a view to improve flexibility of the stent and to allow access to other structures (e.g. side branches/arteries) outside the bounds of the stent.

With reference to Figures 2-10, there are illustrated a number of preferred embodiments of repeating pattern A. For the sake of clarity, numerals in Figures 2-8 have the same final two digits as the corresponding numerals in Figure 1. Thus, for example, the concave-shaped wall is depicted as element 50 in Figure 1, element 150 in Figure 2, element 250 in Figure 3, etc.

Thus, as illustrated in Figure 2, repeating pattern A is comprised of a concave-shaped wall 150 and a convex-shaped wall 160, the former having a flat apex. Further, as illustrated, concave-shaped wall 150 and convex-shaped wall 160 are not equidistant along an axis orthogonal to the longitudinal axis of the stent (not shown). Thus, in this embodiment, the flat apex in concave-shaped wall 150 has

been modified such that it comprises a pair of substantially rounded shoulders 157,158.

With reference to Figure 3, repeating pattern A is similar to the one illustrated in Figure 1. In Figure 3, the flat apex of concave-shaped wall 250 has been modified to provide a pair of rounded shoulders 257,258. Further, a strut 270 has been added to connect segment 254 of concave-shaped wall 250 and segment 264 of convex-shaped wall 260. As illustrated, strut 270 is thinner in dimension that any of the segments making up concave-shaped wall 250 and convex-shaped wall 260. Thus, strut 270 may be considered as a relatively thin retention wire which reconciles the need for retaining flexibility in the strut with mitigating lifting of rounded shoulders 257,258 when the stent is delivered to the target body passageway through a relatively tortuous route.

With reference to Figure 4, repeating pattern A is similar to the one illustrated in Figure 1. In Figure 4, the flat apex of concave-shaped wall 350 has been modified to provide a pair of rounded shoulders 357,358. Further, a curved strut 370 has been added to connect segment 354 of concave-shaped wall 350 and segment 364 of convex-shaped wall 360.

With reference to Figure 5, repeating pattern A is similar to the one illustrated in Figure 1. In Figure 5, the flat apex of concave-shaped wall 450 has been modified to provide a pair of rounded shoulders 457,458. Further, a curved strut 470 has been added to connect segment 454 of concave-shaped wall 450 and segment 464 of convex-shaped wall 460. Further, side walls 435,440 are also curved.

With reference to Figure 6, repeating pattern A is similar to the one illustrated in Figure 1. In Figure 6, concave-shaped wall 550 has been modified to have a flat apex 554 having a pair of rounded shoulders 557,558 and convex-shaped wall 560 has been modified also to have a flat apex 564 having a pair of rounded

shoulders 567,568. Further, a curved strut 570 has been added to connect flat apex 554 of concave-shaped wall 550 and flat apex 564 of convex-shaped wall 560. Further, side walls 535,540 are also curved.

With reference to Figure 7, repeating pattern A is similar to the one illustrated in Figure 1. In Figure 7, concave-shaped wall 650 has been modified to have a flat apex 654 having a pair of rounded shoulders 657,658 and convex-shaped wall 660 has been modified also to have a flat apex 664 having a pair of rounded shoulders 667,668. Further, a curved strut 670 has been added to connect flat apex 654 of concave-shaped wall 650 and flat apex 664 of convex-shaped wall 660. Further, side walls 635,640 are also curved. Still further, walls 661,662 which connect flat apex 664 to side walls 635,640, respectively, and walls 651,652 which connect flat apex 654 to side walls 635,640, respectively, are each curved. It is believed that this design even further enhances the lateral flexibility of the stent.

With reference to Figure 8, repeating pattern A is similar to the one illustrated in Figure 1. In Figure 7, concave-shaped wall 750 has been modified to have a flat apex 754 having a pair of rounded shoulders 757,758 and convex-shaped wall 760 has been modified also to have a flat apex 764 having a pair of rounded shoulders 767,768. Further, a strut 770 has been added to connect flat apex 754 of concave-shaped wall 750 and flax apex 764 of convex-shaped wall 760. Further, side walls 735,740 have been modified to include a sinusoidal (or S-shaped) portion 736,741, respectively, adjacent convex-shaped wall 760. Further, strut 770 has been modified to include a sinusoidal (or S-shaped) portion 771 adjacent flat apex of concave-shaped wall 750. It is believed that this design even further enhances the lateral flexibility of the stent.

With reference to Figure 9, repeating pattern A is similar to the one illustrated in Figure 1. In Figure 9, concave-shaped wall 850 has been modified to have a flat apex 854 having a pair of rounded shoulders 857,858. Further, side

walls 835,840 have been modified to include a pair of sinusoidal (or S-shaped) portions 836,841, respectively, adjacent convex-shaped wall 860. It is believed that this design further enhances the lateral flexibility of the stent illustrated in Figure 2. It should be noted that each sinusoidal (or S-shaped) portion 836,841 in Figure 9 comprises a pair of adjoined curved sections wherein each curved section has an arc of greater than 180° (cf. with the curved sections of sinusoidal (or S-shaped) portions 736,741,771 in Figure 8).

With reference to Figure 10, repeating pattern A is similar to the one illustrated in Figure 1. In Figure 10, concave-shaped wall 950 has been modified to have a flat apex 954 having a pair of rounded shoulders 957,958. Further, a strut 970 has been added to connect flat-apex 954 of concave-shaped wall 950 and segment 964 of convex-shaped wall 960. Further, side walls 935,940 have been modified to include a pair of sinusoidal (or S-shaped) portions 936,941, respectively, adjacent convex-shaped wall 960. Further, strut 970 has been modified to include sinusoidal (or S-shaped) portion 971 adjacent flat apex of concave-shaped wall 950. It should be noted that each sinusoidal (or S-shaped) portion 936,941,971 in Figure 10 comprises a pair of adjoined curved sections wherein each curved section has an arc of greater than 180°. Futher, the curved sections in sinusoidal (or S-shaped) portions 936,941 are of the same size, whereas the curved sections in sinusoidal (or S-shaped) portion 971 are of different size. It is believed that this design even further enhances the lateral flexibility of the stent.

As will be apparent to those of skill in the art, sinusoidal (or S-shaped) portion 971 is offset with respect to sinusoidal (or S-shaped) portions 936,941 in a panel horizontal to the longitudinal axis of repeating pattern A. The offset nature of these sinusoidal (or S-shaped) portions serves to increase the bending points in the stent allowing the stent to bend while avoiding buckling thereof. Thus, the

staged distribution of the sinusoidal (or S-shaped) portions over a large portion of the surface area of the stent serves to improve the flexibility of the stent.

The advantages of the various alternate embodiments illustrated in Figures 2-10 are discussed herein above.

Those of skill in the art will recognize that it is possible to combine various of the alternate embodiments illustrated in Figures 2-10 to derive further designs which are still within the spirit and scope of the present invention. Specifically, a preferred embodiment of the present invention involves combining various of the repeating patterns illustrated in Figures 2-10 to achieve a stent with relatively flexible and rigid regions, for example, as follows:

F-R
F-R-F
R-F-R

wherein F is a relatively flexible region and R is a relatively rigid region. With reference to the embodiments illustrated in Figures 1-7, the relatively flexibility thereof increases (or the relative rigidity thereof decreases) from the design illustrated in Figure 1 progressively through to the design illustrated in Figure 8 and through Figures 10 and 9 (i.e. Figure 9 has the most lateral flexibility). A particularly preferred embodiment of the invention is a stent comprising a first section incorporating the design of Figure 10 and a second section incorporating the design of Figure 9. It is believed that such a multi-sectional design provides a very desirable combination of lateral flexibility (primarily from the design of Figure 9) with post-expansion rigidity (primarily from the design of Figure 10).

Another technique by which the relative flexibility/rigidity may be varied along the length of the stent involves varying the thickness of the segments making

up the polygon discussed hereinabove. Specifically, the thickness of the segments may be varied in the range of from about 0.0015 to about 0.0045 inches, preferably from about 0.0020 to about 0.0040 inches. The lower the thickness in this range, the more flexible the resulting stent design. Conversely, the higher the thickness in this range, the less flexible the resulting stent design. Thus, by judicious selection of segment thickness, the relative flexibility/rigidity of the stent may be varied along its length.

The provision of a stent with a variable relative flexibility/rigidity along its length is believed to be novel. Such a stent would find immediate use in a number of applications. For, example, such a stent would very desirable for implantation in an ostial stenosis (these typically occur in coronary arteries, vein grafts and renal arteries). In this regard, an ostial stenosis is illustrated in Figure 11 thereof. Thus, there is illustrated a right coronary cusp 105, a right coronary artery 110 and an ostial segment 115 of right coronary artery 110. As further illustrated a stenosis 120 presents a narrowing of ostial segment 115. Ideally, a stent capable of implantation into such an ostial stenosis must be of sufficient rigidity after expansion to resist the elastic recoil of the ostial blockage (Region Y in Figure 11). However, a stent of such sufficient rigidity will be deficient since it will either: (i) be retarded in its advance along the artery due to the sharp bend in the right coronary artery (Region X in Figure 11); or (ii) traverse the sharp bend in the right coronary artery but subsequently straighten Region X of right coronary artery 110 thereby increasing the likelihood of tearing the artery. Conversely, a stent of sufficiently flexibility to traverse the sharp bend in the right coronary artery (Region X in Figure 11) is susceptible to recoil in the ostial right coronary artery (Region Y in Figure 11). Accordingly, to the knowledge of the Applicant, there is no known effective manner by which a stent may be used to treat an ostial stenosis of the type illustrated in Figure 11. It is believed that a stent having variable relative

rigidity/flexibility along its length as discussed above is a novel means by which an ostial stenosis may be treated.

The manner by which the present stent is manufactured is not particularly restricted. Preferably, the stent is produced by laser cutting techniques applied to a tubular starting material. Thus, the starting material could be a thin tube of a metal or alloy (non-limiting examples include stainless steel, titanium, tantalum, nitinol, Elgiloy, NP35N and mixtures thereof) which would then have sections thereof cut out to leave repeating pattern A discussed above. Thus, the preferred design of the present stent is one of a tubular wall which is distinct from prior art wire mesh designs wherein wire is conformed to the desired shape and welded in place. The preferred tubular wall design of the present stent facilitates production and improves quality control by avoiding the use of welds and, instead, utilizing specific cutting techniques.

Stent 10 can be implanted using a conventional system wherein a guidewire, catheter and balloon can be used to position and expand the stent. Implantation of mono-tubular stents such as stent 10 is conventional and within the purview of a person skilled in the art. See, for example, any one of United States patents 4,733,665, 4,739,762, 5,035,706, 5,037,392, 5,102,417, 5,147,385, 5,282,824, 5,316,023 and any of the references cited therein or any of the references cited hereinabove. When the present stent is constructed as a bifurcated stent, it may be implanted using the procedure outlined in the '997 patent application incorporated herein by reference. Such a bifurcated stent may be manufactured, inter alia, by any of the methods disclosed in the Canadian patent application number 2,175,720 filed in Applicant's name on May 3, 1996, the contents of which are hereby incorporated by reference.

It will be apparent to those of skill in the art that implantation of stent 10 can be accomplished by various other means. For example, it is contemplated that the

stent can be made of a suitable material which will expand when a certain temperature is reached. In this embodiment, the material may be a metal alloy (e.g. nitinol) capable of self-expansion at a temperature of at least about 30°C, preferably in the range of from about 30° to about 40°C. In this embodiment, the stent could be implanted using a conventional catheter and the radially outward force exerted on the stent would be generated within the stent itself. Further, stent 10 can be designed to expand upon the application of mechanical forces other than those applied by a balloon/catheter. For example, it is possible to implant stent 10 using a catheter equipped with a resisting sleeve or retaining membrane which may then be removed with the catheter once the stent is in position thereby allowing the stent to expand. Thus, in this example, the stent would be resiliently compressed and would self-expanded once the compressive force (i.e. provided by the sleeve or membrane) is removed.

As will be appreciated by those of skill in the art, repeating pattern A has been described hereinabove and illustrated in Figure 1 in respect of a monotubular stent. Repeating pattern A and all of the features relating thereto illustrated in and described with reference to Figures 1-8 is equally applicable to a bifurcated stent such as the one described and illustrated in the '997 application discussed hereinabove, the contents of which are hereby incorporated by reference.

While this invention has been described with reference to illustrative embodiments, this description is not intended to be construed in a limiting sense. Various modifications of the illustrative embodiments, as well as other embodiments of the invention , will be apparent to persons skilled in the art upon reference to this description. It is therefore contemplated that the appended claims will cover any such modifications or embodiments.

What is claimed is:

1. An expandable stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality intersecting members arranged to define a first repeating pattern comprised of a polygon having a pair of side walls substantially parallel to the longitudinal axis, a concave-shaped first wall having a first apex and a convex-shaped second wall having a second apex, the first wall and the second wall connecting the side walls, at least one of the first apex and the second apex being substantially flat, the stent being expandable from a first, contracted position to a second, expanded position upon the application of a radially outward force on the stent.

2. The stent defined in claim 1, wherein both the first apex and the second apex are substantially flat.

3. The stent defined in any one of claims 1-2, wherein the first apex and the second apex are of different length.

4. The stent defined in claim 2, wherein the first apex and the second apex are of the same length.

5. The stent defined in any one of claims 2 and 4, wherein the first wall and the second wall are substantially equidistant from one another along an axis parallel to the longitudinal axis.

6. The stent defined in any one of claims 1-5, wherein one of the first apex and the second apex is substantially arcuate.

7. The stent defined in any one of claims 1-6, further comprising a strut connecting the first apex to the second apex.

8. The stent defined in claim 7, wherein the strut is curved with respect to the longitudinal axis.

9. The stent defined in claim 8, wherein the strut has length of up to about 35% greater than the distance between the first apex and the second apex.

10. The stent defined in claim 8, wherein the strut has a length up to about 15% greater than the distance between the first apex and the second apex.

11. The stent defined in claim 8, wherein the strut has a length in the range of from about 2% to about 8% greater than the distance between the first apex and the second apex.

12. The stent defined in claim 8, wherein the strut has a length in the range of from about 3% to about 7% greater than the distance between the first apex and the second apex.

13. The stent defined in any one of claims 7-12, wherein the strut comprises an S-shaped portion.

14. The stent defined in claim 13, wherein the S-shaped portion comprises a pair of joined curved sections wherein each curved section has an arc of about 180°.

15. The stent defined in claim 13, wherein the S-shaped portion comprises a pair of joined curved sections wherein each curve section has an arc of greater than 180°.

16. The stent defined in any one of claims 14-15, wherein the curved sections are of substantially the same size.

17. The stent defined in any one of claims 14-15, wherein the curved sections are of different size.

18. The stent defined in any one of claims 1-17, wherein the side walls are substantially equidistant from one another along an axis orthogonal to the longitudinal axis of the stent.

19. The stent defined in any one of claims 1-17, wherein one of the side walls is curved with respect to the longitudinal axis.

20. The stent defined in claim 19, wherein the one of the side walls which is curved has a length up to about 35% greater than the distance between the respective termini of the first wall and the second wall.

21. The stent defined in claim 19, wherein the one of the side walls which is curved has a length up to about 15% greater than the distance between the respective termini of the first wall and the second wall.

22. The stent defined in claim 19, wherein the one of the side walls which is curved has a length in the range of from about 2% to about 8% greater than the distance between the respective termini of the first wall and the second wall.

23. The stent defined in claim 19, wherein the one of the side walls which is curved has a length in the range of from about 3% to about 7% greater than the distance between the respective termini of the first wall and the second wall.

24. The stent defined in any one of claims 1-17, wherein both of the side walls are curved with respect to the longitudinal axis.

25. The stent defined in claim 24, wherein the side walls have a length up to about 35% greater than the distance between the respective termini of the first wall and the second wall.

26. The stent defined in claim 24, wherein the side walls have a length up to about 15% greater than the distance between the respective termini of the first wall and the second wall.

27. The stent defined in claim 24, wherein the side walls have a length in the range of from about 2% to about 8% greater than the distance between the respective termini of the first wall and the second wall.

28. The stent defined in claim 24, wherein the side walls have a length in the range of from about 3% to about 7% greater than the distance between the respective termini of the first wall and the second wall.

29. The stent defined in any one of claims 1-28, wherein at least one of the pair of side walls comprises an S-shaped portion.

30. The stent defined in claim 29, wherein both of the side walls comprises an S-shaped portion.

31. The stent defined in any one of claims 29-30, wherein the S-shaped portion comprises a pair of joined curved sections wherein each curve section has an arc of about 180°.

32. The stent defined in any one of claims 29-30, wherein the S-shaped portion comprises a pair of joined curved sections wherein each curved section has an arc of greater than 180°.

33. The stent defined in any one of claims 31-32, wherein the curved sections are of substantially the same size.

34. The stent defined in any one of claims 31-32, wherein the curved sections are of different size.

35. The stent defined in any one of claims 1-34, wherein the stent is constructed of stainless steel.

36. The stent defined in any one of claims 1-34, wherein the stent is constructed of a self-expanding material.

37. The stent defined in claim 36, wherein the self-expanding material is nitinol.

38. The stent defined in claim 36, wherein the self-expanding material expands at a temperature of greater than about 30°C.

39. The stent defined in claim 36, wherein the self-expanding material expands at a temperature of in the range of from about 30° to about 40°C.

40. The stent defined in any one of claims 1-39, in the form of a bifurcated stent comprising a proximal end and a distal end in communication with one another, the proximal end comprising a primary passageway and the distal end comprising a pair of secondary passageways.

41. The stent defined in claim 40, wherein the primary passageway is connected to the each of the secondary passageways at an intersection point.

42. The stent defined in claim 41, wherein the intersection point is reinforced with respect to the remainder of the stent.

43. The stent defined in any one of claims 41-42, wherein the intersection point is porous.

44. The stent defined in claim 43, wherein the porosity of the intersection point is defined by a plurality intersecting members.

45. The stent defined in claim 44, wherein the intersecting members define a second repeating pattern.

46. The stent defined in claim 45, wherein the second repeating pattern is a polygon having a pair of side walls substantially parallel to the longitudinal axis of the primary passageway, a concave-shaped first wall and a convex-shaped second wall connecting the side walls, the side walls being substantially equidistant along an axis which is parallel to the longitudinal axis of the primary passageway, and a reinforcing bar disposed between and substantially parallel to the pair of side walls.

47. The stent defined in claim 46, wherein the reinforcing bar is disposed substantially equidistant from each of the side walls.

48. The stent defined in any of one of claims 40-47, wherein the primary passageway has a substantially circular cross-section.

49. The bifurcated stent defined in any one of claims 40-48, wherein each of the secondary passageways has a substantially circular cross-section.

50. The bifurcated stent defined in any one of claims 48-49, wherein the cross-sectional area of the primary passageway is substantially the same as the sum of the cross-sectional areas of each secondary passageway.

51. The stent defined in any one of claims 40-50, wherein the distal end is flexible with respect of the remainder of the stent.

52. The stent defined in any one of claims 40-51, wherein the proximal end is flexible with respect to the remainder of the stent.

53. The stent defined in any one of claims 40-52, wherein the length of each of the primary passageway and the secondary passageways is substantially the same.

54. The stent defined in any one of claims 40-53, wherein the length of each of the primary passageway and the secondary passageways is different.

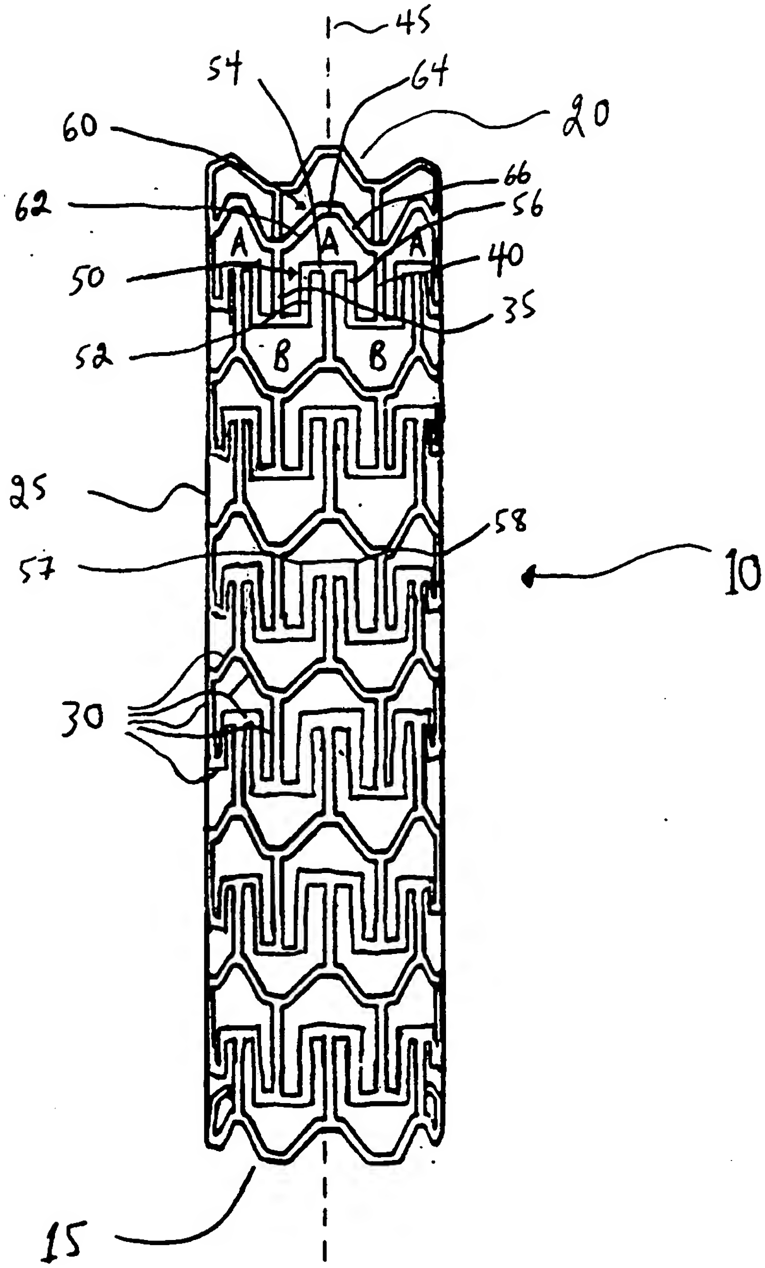


FIGURE 1

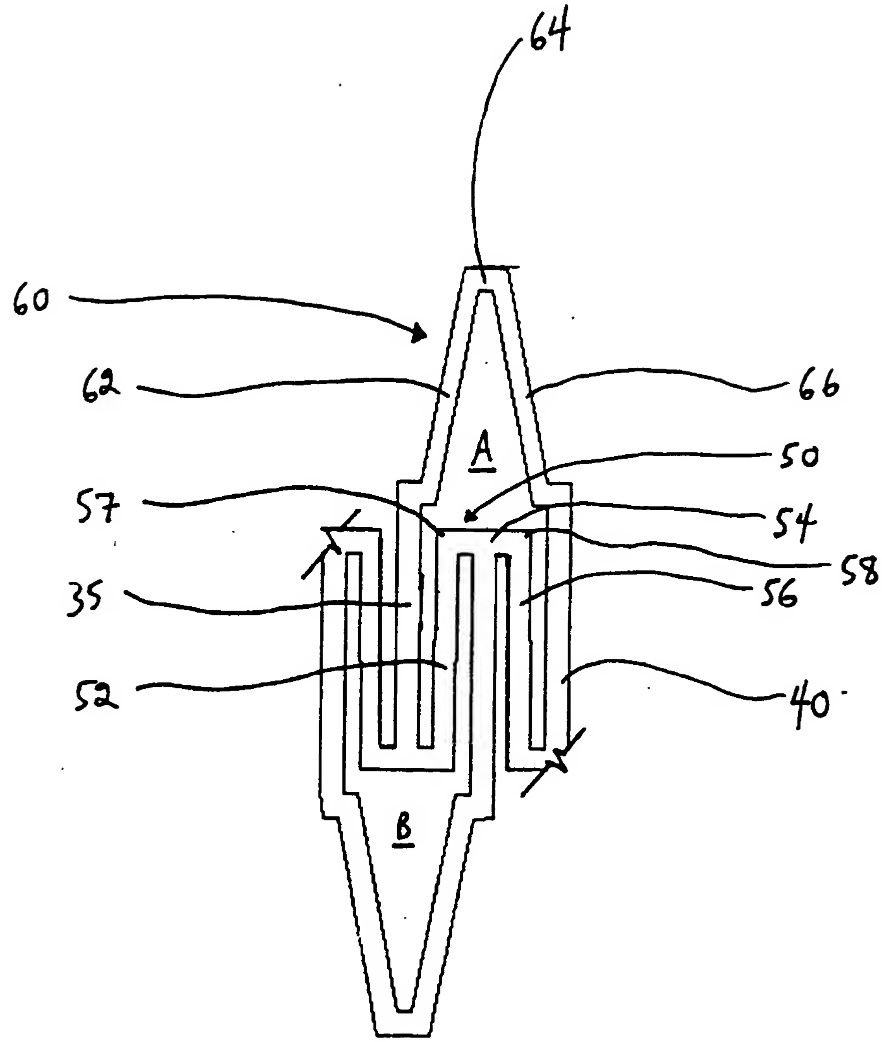


FIGURE 1A

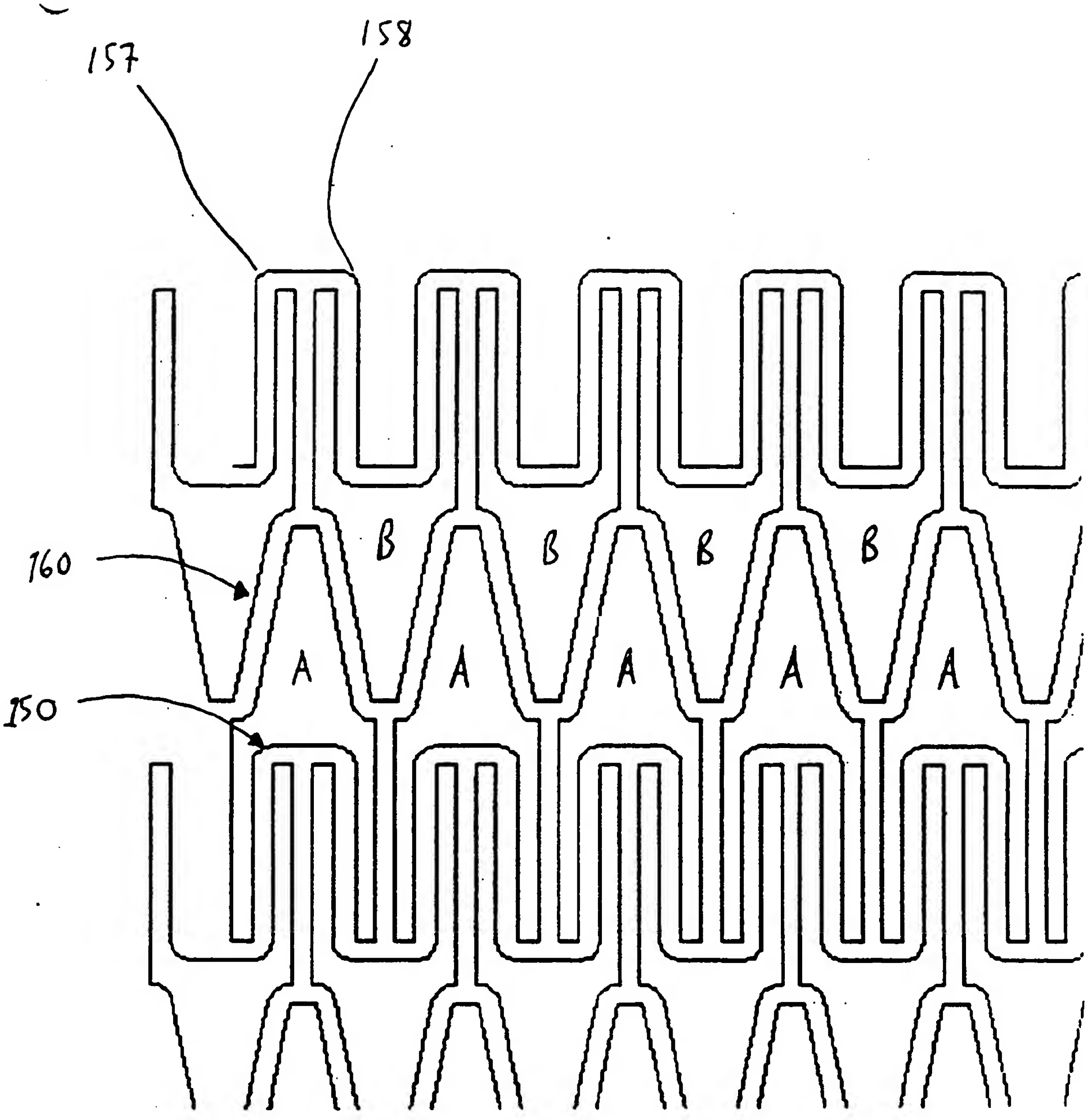


FIGURE 2

McCARTHY TÉTRAULT
AGENTS FOR THE APPLICANT

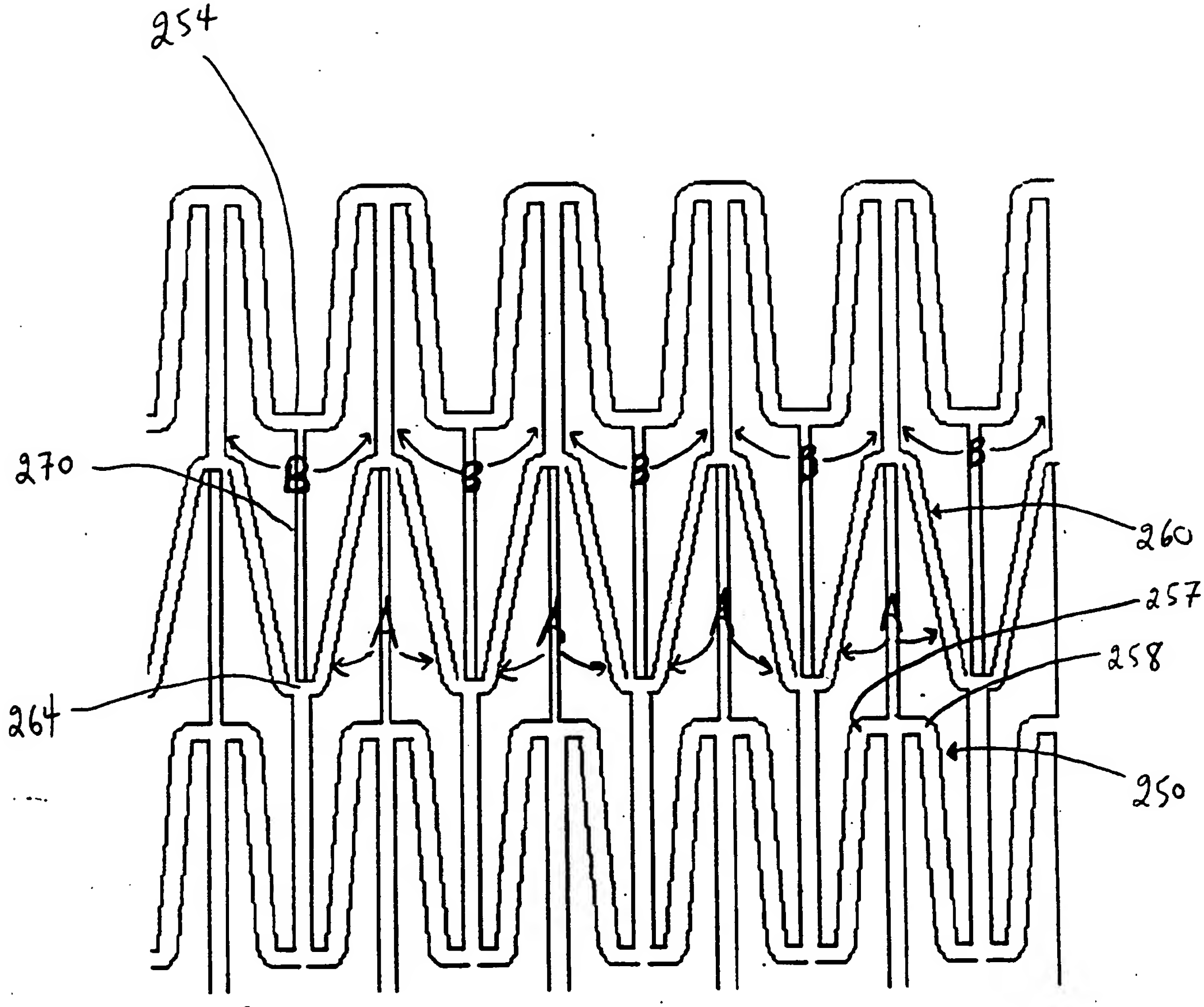


FIGURE 3

MCCARTHY TÉTRAULT
AGENTS FOR THE APPLICANT

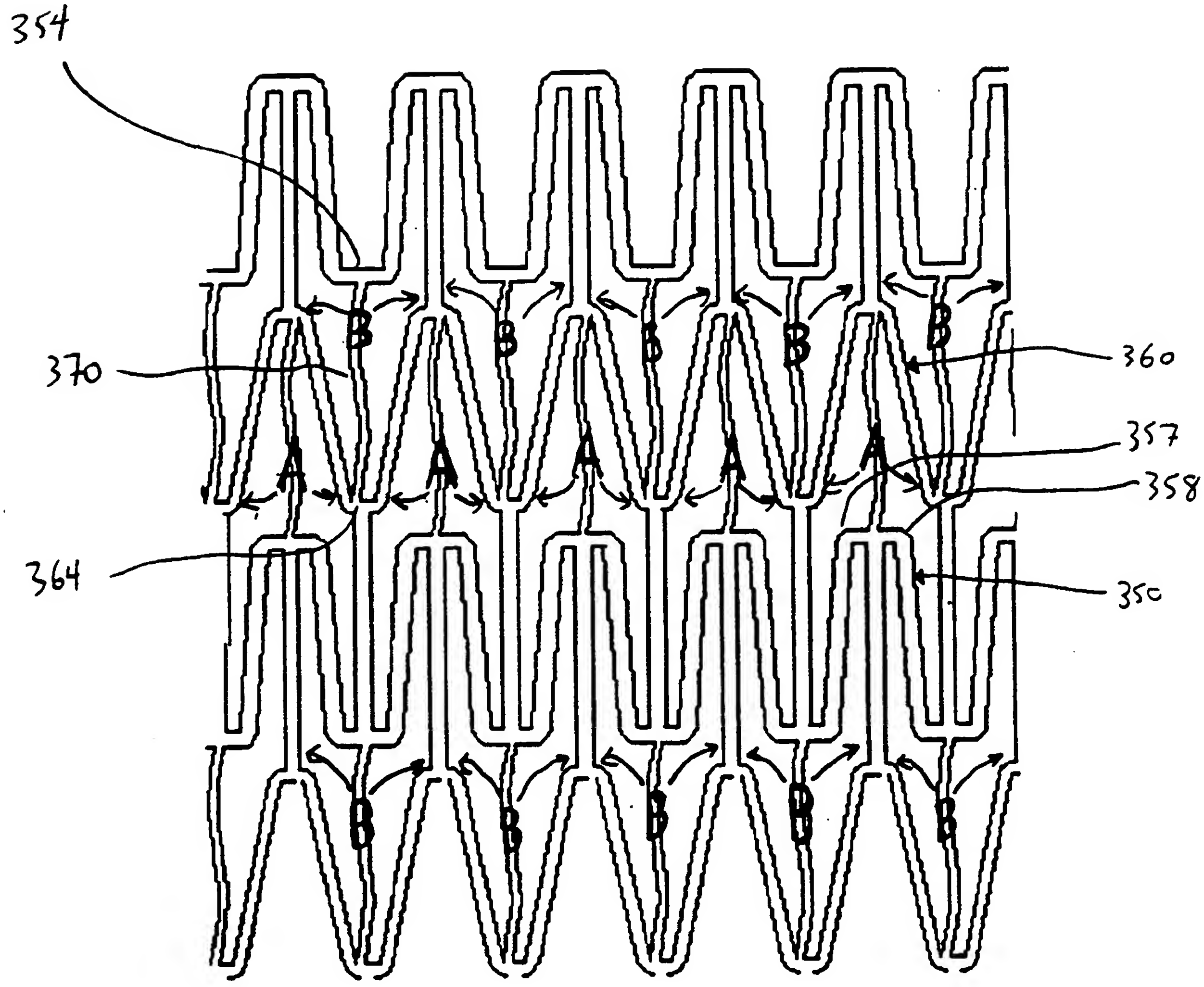


FIGURE 4

McCARTHY TÉTRAULT
AGENTS FOR THE APPLICANT

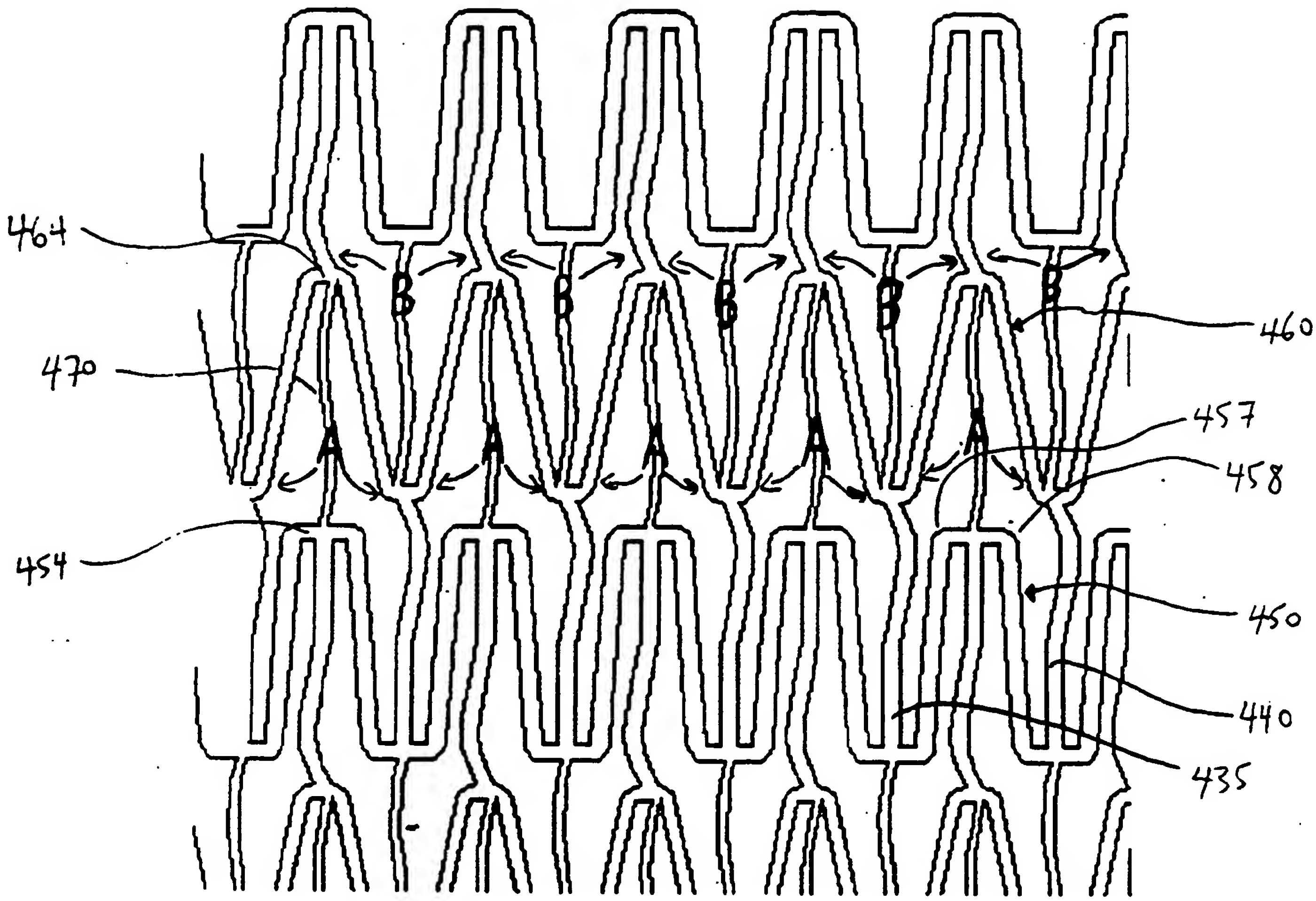


FIGURE 5

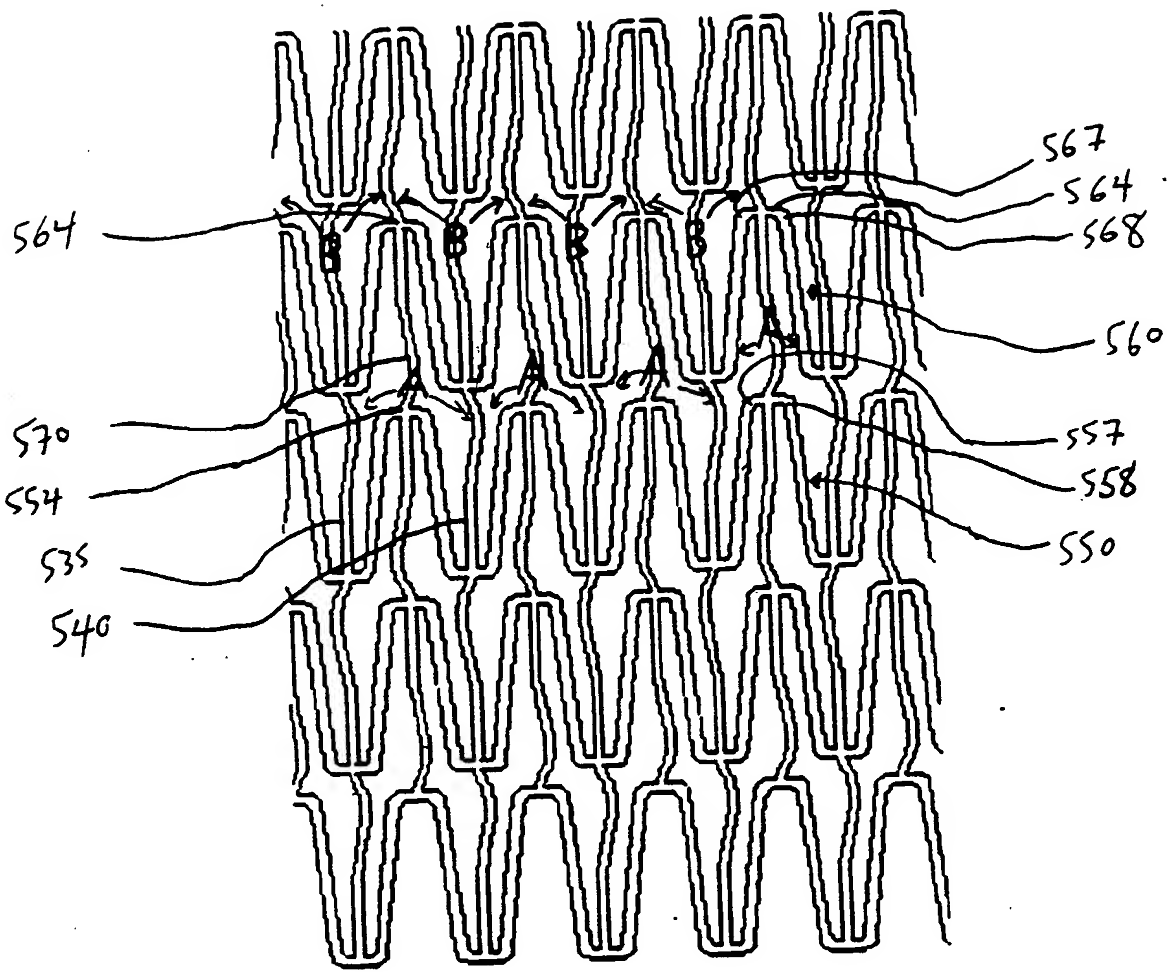


FIGURE 6

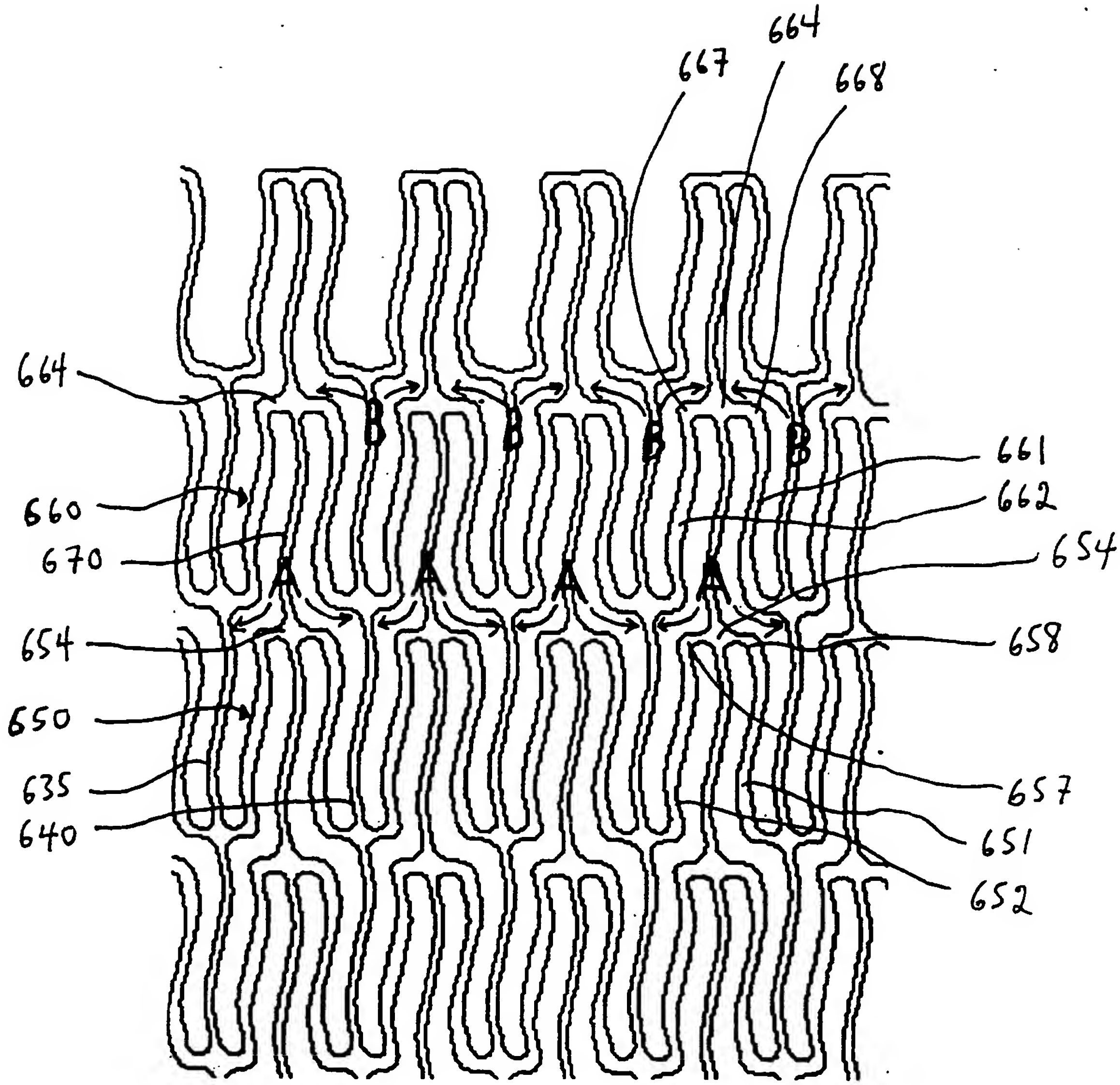


FIGURE 7

McCARTHY TÉTRAULT
AGENTS FOR THE APPLICANT

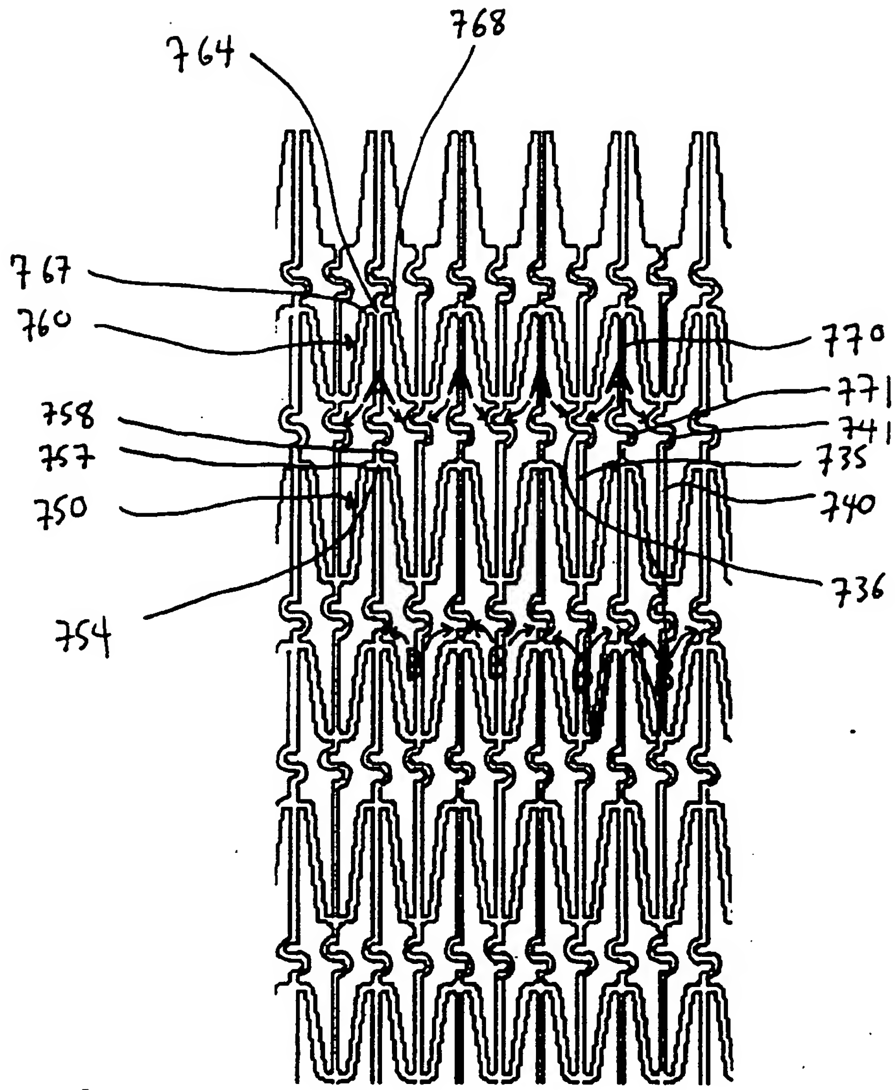


FIGURE 8

McCARTHY TÉTRAULT
AGENTS FOR THE APPLICANT

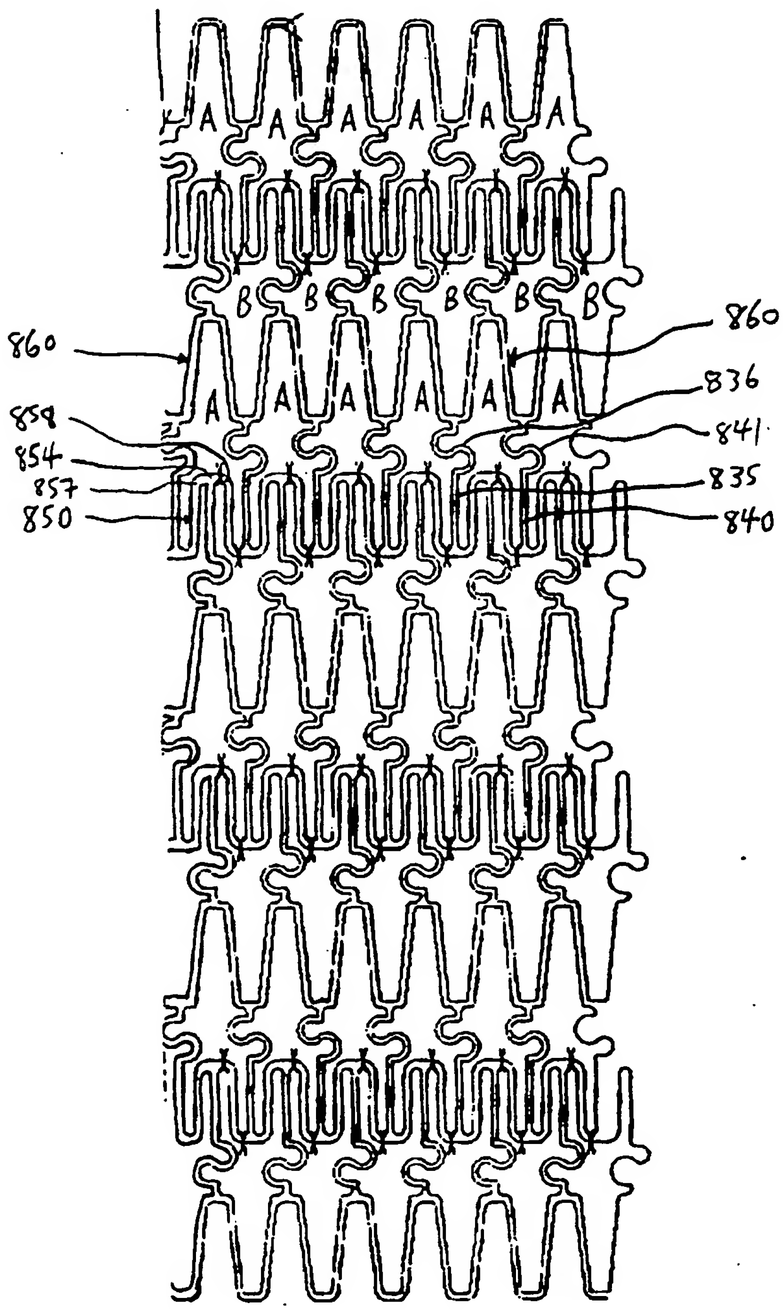


FIGURE 9

McCARTHY TÉTRAULT
AGENTS FOR THE APPLICANT

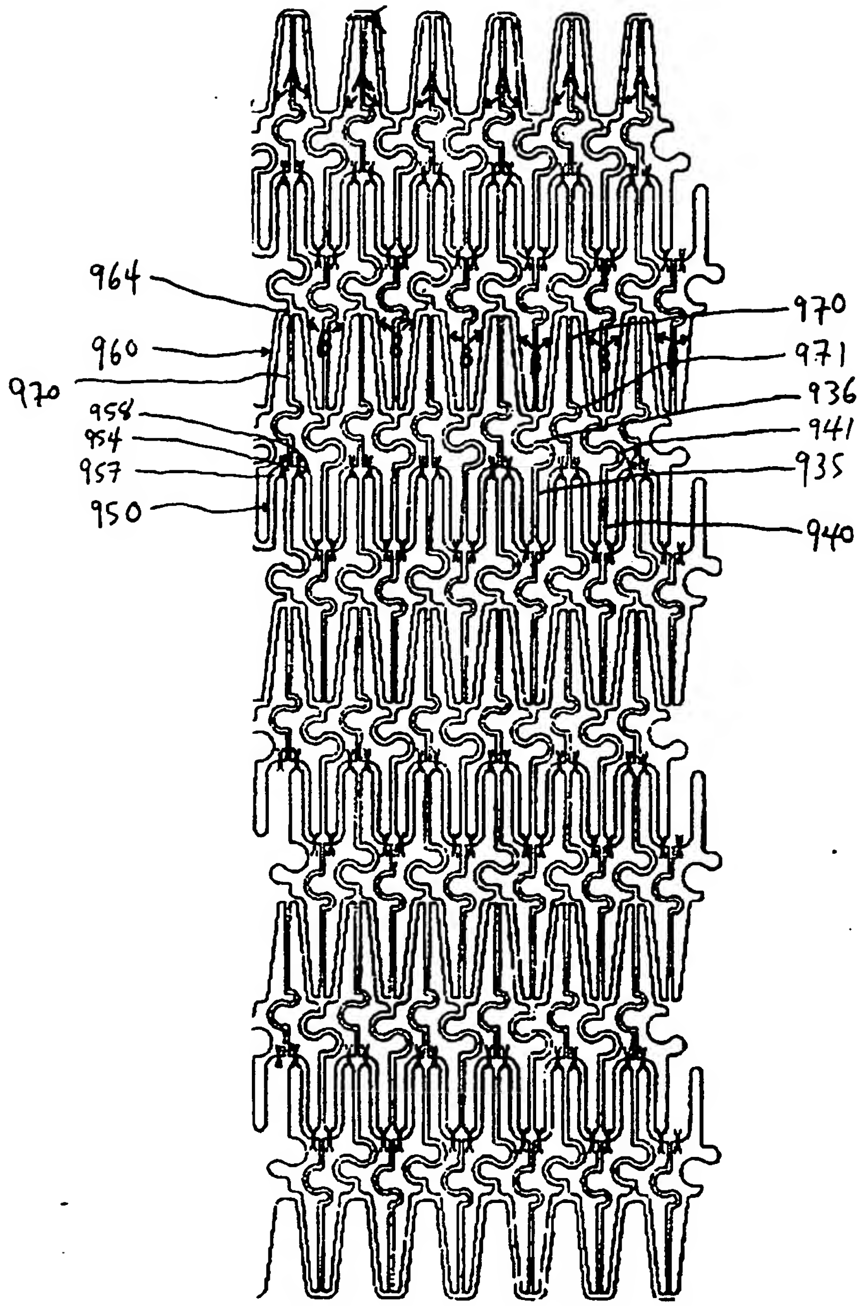


FIGURE 10

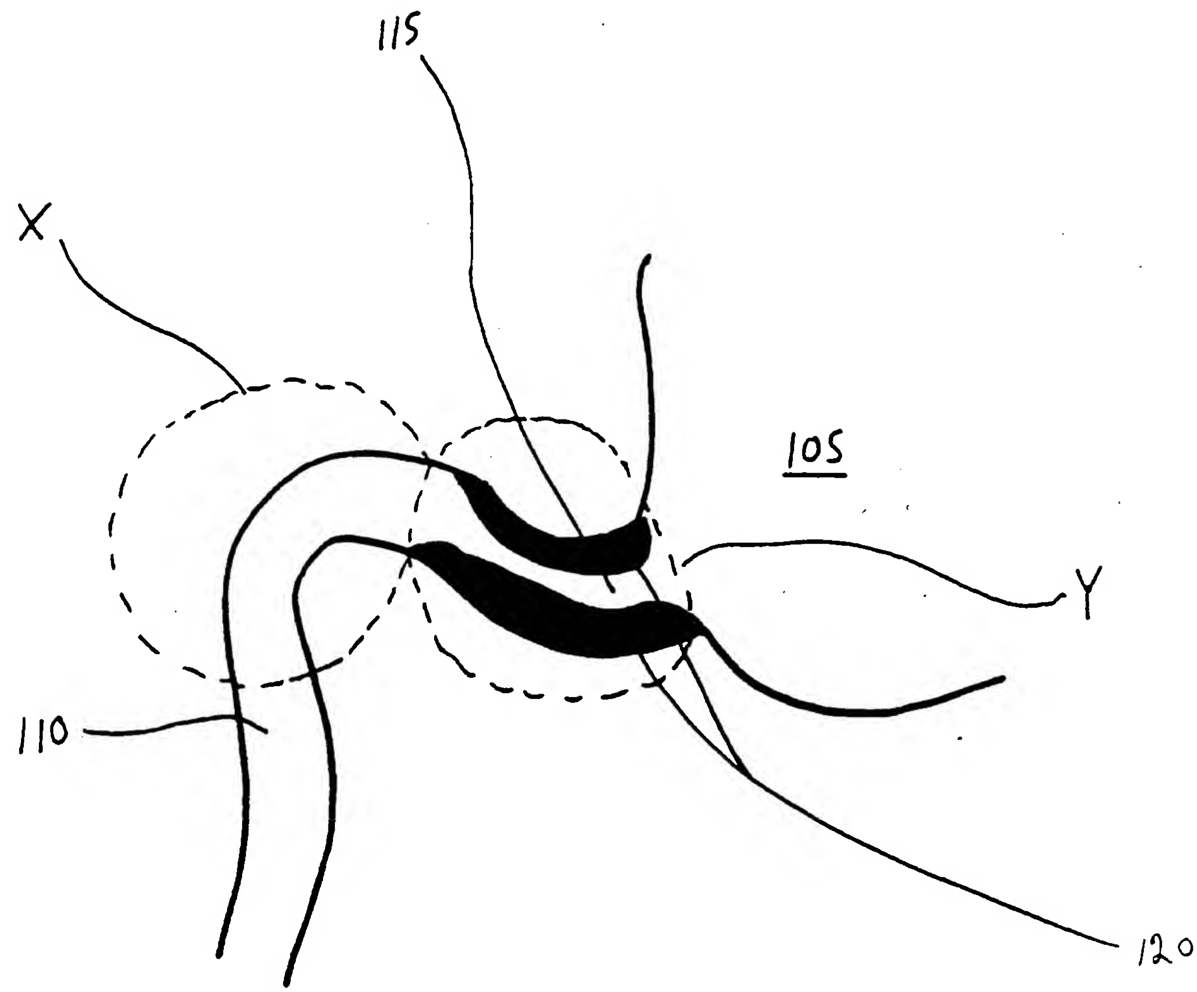


FIGURE 11

MCCARTHY TÉTRAULT
AGENTS FOR THE APPLICANT